

Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-Aug-2024
Document Type: USP Monographs
DocId: GUID-3CD9DCAC-DCA1-41B4-905F-59BB000A36B_2_en-US
DOI: https://doi.org/10.31003/USPNF_M4257_02_01
DOI Ref: 3o4wrf

© 2025 USPC
Do not distribute

Add the following:

▲Plerixafor Injection

DEFINITION
Plerixafor Injection is a sterile isotonic solution of Plerixafor in Water for Injection. It contains NLT 90.0% and NMT 110.0% of the labeled amount of plerixafor (C₂₈H₅₄N₈) with no preservatives.

IDENTIFICATION

- **A.** The UV spectrum of the plerixafor peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

• **PROCEDURE**

Solution A: [Methanol](#) and [water](#) (8.5: 91.5). To each liter of the solution, add 1 mL of [trifluoroacetic acid](#).

Solution B: [Methanol](#) and [water](#) (50:50). To each liter of the solution, add 1 mL of [trifluoroacetic acid](#).

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	100	0
20	100	0
32	48	52
33	10	90
34	10	90

Diluent: 0.05 N [hydrochloric acid](#)

Standard solution: 2 mg/mL of [USP Plerixafor RS](#) in *Diluent*. Sonicate to dissolve.

Sample solution: Nominally 2 mg/mL of plerixafor from Injection prepared as follows. Empty and pool the contents of a suitable number of vials into a suitable glass container to obtain NLT 22 mL of the solution. Mix and transfer 5 mL of the pooled sample into a 50-mL volumetric flask and dilute with *Diluent* to volume.

Chromatographic system
(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 230 nm. For *Identification A*, use a diode array detector in the range of 200–400 nm.

Column: 4.6-mm × 25-cm; 5-µm packing [L1](#)

Column temperature: 45°

Flow rate: 1 mL/min

Injection volume: 10 µL

System suitability
Sample: *Standard solution*
Suitability requirements

Tailing factor: NMT 6.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of plerixafor ($C_{28}H_{54}N_8$) in the portion of Injection taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of plerixafor from the *Sample solution*

r_S = peak response of plerixafor from the *Standard solution*

C_S = concentration of [USP Plerixafor RS](#) in the *Standard solution* (mg/mL)

C_U = nominal concentration of plerixafor in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

IMPURITIES

• ORGANIC IMPURITIES

Solution A, Solution B, Mobile phase, Diluent, Sample solution, and Chromatographic system: Proceed as directed in the Assay.

System suitability solution: 2 mg/mL of [USP Plerixafor System Suitability Mixture RS](#) in *Diluent*. Sonicate to dissolve.

Standard solution: 0.004 mg/mL of [USP Plerixafor RS](#) in *Diluent*

Sensitivity solution: 0.002 mg/mL of [USP Plerixafor RS](#) in *Diluent* from the *Standard solution*

System suitability

Samples: *System suitability solution*, *Standard solution*, and *Sensitivity solution*

[NOTE—Plerixafor 4-benzyl analog and plerixafor 8-benzyl analog coelute under these chromatographic conditions. The relative retention times in [Table 2](#) are provided as information that could aid in peak assignment.]

Table 2

Name	Relative Retention Time
Plerixafor benzyl alcohol ^a	0.9
Plerixafor	1.0
Plerixafor 4-benzyl analog ^b and plerixafor 8-benzyl analog ^c	2.5
Plerixafor 11-benzyl analog ^d	2.7

^a {4-[(1,4,8,11-Tetraazacyclotetradecan-1-yl)methyl]phenyl}methanol.

^b 1,4-Bis{4-[(1,4,8,11-tetraazacyclotetradecan-1-yl)methyl]benzyl}-1,4,8,11-tetraazacyclotetradecane.

^c 1,8-Bis{4-[(1,4,8,11-tetraazacyclotetradecan-1-yl)methyl]benzyl}-1,4,8,11-tetraazacyclotetradecane.

^d 1,11-Bis{4-[(1,4,8,11-tetraazacyclotetradecan-1-yl)methyl]benzyl}-1,4,8,11-tetraazacyclotetradecane.

Suitability requirements

Resolution: NLT 1.0 between plerixafor and plerixafor benzyl alcohol, *System suitability solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Signal-to-noise ratio: NLT 10, *Sensitivity solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of any unspecified degradation product in the portion of Injection taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times F \times 100$$